IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC. Defendant.	C.A. No. 21-1015-JLH **DEMAND FOR JURY TRIAL**
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff/Counter-Defendants.	

[PROPOSED] AMENDED JOINT PRETRIAL ORDER

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Dated: November 26, 2024

LIST OF EXHIBITS IN JOINT PRETRIAL ORDER

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This matter comes before the Court at a final pretrial conference held pursuant to Rule 16 of the Federal Rules of Civil Procedure. The Pretrial Conference is scheduled for December 9, 2024. D.I. 634. Jury selection before a Magistrate Judge is scheduled for December 13, 2024. D.I. 597. A five-day jury trial is scheduled to begin on December 16, 2024. *Id.*

I. NATURE OF THE CASE

This is an action involving patent infringement, patent invalidity, inequitable conduct, and *Walker Process* fraud. Plaintiff Nippon Shinyaku and Counter-Plaintiffs Sarepta and UWA initially asserted claims for patent infringement of the NS Patents and the Wilton Patents, respectively.

Nippon Shinyaku asserted claims for patent infringement of the NS Patents against Sarepta arising out of Sarepta's manufacture, use, sale, offers to sell within the United States, and/or importation into the United States of VYONDYS 53®, also known as golodirsen, and Sarepta's intentional encouragement of physicians to administer VYONDYS 53®. Nippon Shinyaku alleged that Sarepta's infringement is willful. Nippon Shinyaku seeks a reasonable royalty for Sarepta's alleged past and future infringement under 35 U.S.C. § 284 as well as lost profits. Nippon Shinyaku also seeks pre-judgment and post-judgment interest, an award of enhanced damages for alleged willful infringement, and an award of attorneys' fees and costs.

Sarepta and UWA asserted counterclaims for infringement of the Wilton Patents against Nippon Shinyaku and Counter-Defendant NS Pharma arising out of their manufacture, use, sale, offers to sell within the United States, and/or importation into the United States of VILTEPSO®, also known as viltolarsen, and their intentional encouragement of physicians and patients to administer VILTEPSO®. Sarepta and UWA alleged that Nippon Shinyaku's and NS Pharma's infringement is willful. Sarepta and UWA seek a reasonable royalty for Nippon Shinyaku's and NS Pharma's alleged past and future infringement under 35 U.S.C. § 284 as well as lost profits.

Sarepta and UWA also seek pre-judgment and post-judgment interest, an award of enhanced damages for alleged willful infringement, and an award of attorneys' fees and costs.

In Nippon Shinyaku's operative complaint (D.I. 86), Nippon Shinyaku further asserted claims for declaratory judgment of invalidity of the Wilton Patents.

In its Answer (D.I. 328), Sarepta denied that it is liable for the asserted causes of action and asserted a counterclaim for declaratory judgment of invalidity of the NS Patents.

Nippon Shinyaku and NS Pharma answered Sarepta's and UWA's respective counterclaims, denying they are liable for the asserted causes of action. D.I. 344. Additionally, Nippon Shinyaku and NS Pharma asserted counterclaims against Sarepta for unenforceability of the Wilton Patents due to inequitable conduct and for *Walker Process* fraud based on Sarepta's alleged violations of the Sherman Act, 15 U.S.C. §§ 1 *et seq.* by asserting patents that were allegedly obtained by fraud on the USPTO against Nippon Shinyaku and NS Pharma in an attempted effort to unlawfully acquire or maintain monopoly power through improper means. Sarepta answered Nippon Shinyaku's and NS Pharma's counterclaims, denying it is liable for the asserted causes of action. D.I. 347. Sarepta further moved to bifurcate and stay Nippon Shinyaku's and NS Pharma's *Walker Process* fraud claim, (D.I. 345), and Nippon Shinyaku and NS Pharma opposed this motion (D.I. 356).

Sarepta later voluntarily dismissed in part its defenses of no direct infringement, induced infringement, and contributory infringement of claims 1-3 of U.S. Patent No. 10,385,092, claims 1-2 of U.S. Patent No. 10,407,461, and claims 1-2 of U.S. Patent No. 10,487,106 (D.I. 328 at 26, Third Defense) with prejudice, as well as voluntarily dismissing in part its defenses of induced and contributory infringement of claims 1-12 of U.S. Patent No. 10,647,741 and claims 1-4 of U.S. Patent No. 10,662,217 (D.I. 328 at 26, Third Defense) with prejudice. D.I. 475, ¶¶ 1-2. Sarepta

also narrowed its invalidity defenses and counterclaims to include obviousness defenses only (not anticipation). D.I. 526.

Nippon Shinyaku and NS Pharma later voluntarily dismissed in part their counterclaim of *Walker Process* fraud under Section 2 of the Sherman Act (D.I. 344, Counterclaim Claim XI) to the extent it relates to actual monopolization with prejudice. Nippon Shinyaku and NS Pharma are proceeding with their *Walker Process* fraud Counterclaim Claim XI to the extent it relates to attempted monopolization. D.I. 475, ¶ 3.

On April 18, 2024, the Court granted-in-part Sarepta's motion to bifurcate and stay Nippon Shinyaku's and NS Pharma's *Walker Process* fraud claim. D.I. 529. The Court bifurcated "NS's antitrust claim from the substantive patent issues for trial." *Id.* The Court further ordered, based on the parties agreement "that both sides' inequitable conduct claims may properly be tried to the bench" and "that the Court's findings and conclusions regarding NS's inequitable conduct claim will be binding on the parties with respect to the inequitable conduct elements of NS's Walker Process antitrust claim." *Id.*; *see also* Apr. 18, 2024 Status Conference Tr. at 8:11-9:6. The Court ordered that there will be a "bench trial on inequitable conduct . . . with evidence pertaining solely to inequitable conduct being presented to the Court after the jury is released [each day] and/or while the jury is deliberating." *Id.*

On April 29, 2024, the parties filed a Proposed Joint Pretrial Order. D.I. 536. In it, Nippon Shinyaku sought dismissal with prejudice of its claims of infringement for all NS Patent claims except five claims from five patents identified on the attached Exhibit 1. *See* D.I. 536 ¶ 78. Nippon Shinyaku and NS Pharma also sought dismissal with prejudice of its claim that the Wilton Patents are invalid under 35 U.S.C. § 103. D.I. 536 ¶ 78. Sarepta sought dismissal with prejudice of its

claims of infringement for all Wilton Patent claims except the one claim from one patent identified on the attached Exhibit 1. *See* D.I. 536 ¶ 78.

In this pleading, Nippon Shinyaku and Sarepta and UWA again withdraw their claims of infringement of specified patent claims (*see infra* § XV). As a result, Nippon Shinyaku asserts five claims from five NS Patents and Sarepta asserts one claim from one patent, the Wilton Patent. **[Sarepta's Proposal:** As discussed *infra* § XVI, given that this is a short trial where the jury will be tasked with understanding complicated technology, the five NS Patents all come from the same patent family, the specifications of all five NS Patents are substantively identical, that Nippon Shinyaku's claimed damages are independent of the number of patents or claims asserted, and that the invalidity of all five claims from the five NS Patents will stand or fall together, Nippon Shinyaku is further limited to asserting claims from only one NS Patent.**]** **[Nippon Shinyaku's and NS Pharma's Proposal:** As discussed *infra* § XVI, the NS Patent claims are not identical, and the number of asserted patents and claims is not unreasonable. Sarepta has not identified any legal basis for limiting Nippon Shinyaku to a single patent and claim. As such, Nippon Shinyaku should not be further limited in the number of asserted patents and claims.]

Sarepta also again withdraws its breach of contract claim (*see infra* § XV).

II. JURISDICTION

The Court's subject matter jurisdiction is not disputed and is based on 28 U.S.C. §§ 1331, 1332(a), 1367(a), 1338(a), 2201, and 2202. No party disputes personal jurisdiction for purposes of this action.

III. FACTS

A. Uncontested Facts

1. A joint statement of uncontested facts is set forth in **Exhibit 2**. These proposed uncontested facts require no proof at trial and will become part of the evidentiary record in this

case. Subject to the Court's approval, any party, with prior notice to the other party, may read any or all of the uncontested facts to the jury or Court, as long as entire facts are read (i.e., the entire numbered paragraph) and will be charged for the time used to do so. The parties reserve the right to modify or supplement the joint statement of uncontested facts to the extent necessary before they are entered into the evidentiary record to reflect fairly the Court's rulings on any motions or subsequent orders of the Court, or by agreement of the parties.

2. Nippon Shinyaku and NS Pharma do not intend to refer to themselves collectively as "NS." However, the term "NS" is used in the "NS Patents" abbreviation and might be used by witnesses during trial. The parties agree that the use of "NS Patents" and, to the extent that any party uses the term "NS" to refer collectively to Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. at trial, it is not a waiver or admission of any kind, including an admission that Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. are not separate entities.

B. Statement of Contested Facts to be Litigated at Trial

3. Nippon Shinyaku's and NS Pharma's statement of issues of fact that remain to be litigated and expected proof is attached as **Exhibit 3**.

4. Sarepta's and UWA's statement of issues of fact that remain to be litigated and expected proof is attached as **Exhibit 4**.

5. The parties reserve the right to modify or supplement their statements of fact that remain to be litigated to the extent necessary to reflect fairly the Court's rulings on any motions or subsequent orders of the Court or by agreement of the parties.

IV. ISSUES OF LAW

6. Nippon Shinyaku's and NS Pharma's statement of issues of law that remain to be litigated is attached as **Exhibit 5**.

7. Sarepta's and UWA's statement of issues of law that remain to be litigated is attached as **Exhibit 6**.

8. The Court's anticipated rulings on the pending motions *in limine* and motions to exclude may impact the issues of law to be litigated. Further, on November 19, 2024, Nippon Shinyaku and NS Pharma identified untimely and improper opinions expressed in the supplemental opinions from Sarepta's expert John Jarosz served on November 5, 2024. As described further *infra* §XVI.B., Sarepta objects to Nippon Shinyaku's untimely disclosure of Donald Foy as trial witness, as Nippon Shinyaku did not disclose Mr. Foy on its Rule 28 Initial Disclosures until November 8, 2024 and failed to show that Mr. Foy has personal knowledge of any relevant information. Nippon Shinyaku and NS Pharma dispute Sarepta's allegations that the disclosure of Mr. Foy was untimely or that he lacks personal knowledge. These disputes may also impact the issues of law to be litigated.

V. EXHIBITS

A. Exhibits

9. Nippon Shinyaku's and NS Pharma's trial exhibit list is attached as **Exhibit 7**. Nippon Shinyaku and NS Pharma identified their exhibits starting with PTX1. Nippon Shinyaku and NS Pharma reserve the right to rely on additional exhibits for the purposes of impeachment. Exhibits relied upon solely for purposes of impeachment shall not be admitted into evidence unless identified on a trial exhibit list.

10. Sarepta's and UWA's trial exhibit list is attached as **Exhibit 8**. Sarepta and UWA identified their exhibits starting with DTX1. Sarepta and UWA reserve the right to rely on additional exhibits for purposes of impeachment. Exhibits relied upon solely for purposes of impeachment shall not be admitted into evidence unless identified on a trial exhibit list.

11. A list of the joint trial exhibits is attached as **Exhibit 9**. Joint trial exhibits will be identified with JTX numbers starting with JTX1. Exhibits relied upon solely for purposes of impeachment shall not be admitted into evidence unless identified on a trial exhibit list.

12. To the extent that there are identical exhibits identified by distinct numbers on the parties' exhibit lists that are offered and accepted into evidence at trial, the parties shall meet and confer to ensure that such exhibits are subsequently referred to by a single exhibit number. The parties reserve the right to admit PTX and DTX versions of the same document.

13. The descriptions of the documents in Exhibits 7, 8, and 9 are for the convenience of the parties and the Court only and do not constitute admissions about the content or admissibility of the documents described, or other aspects of the documents.

14. A side's failure to introduce any exhibit appearing on its list shall not be commented on during trial.

15. The parties have entered into a stipulation regarding document authenticity, which they incorporate fully herein by reference. *See* D.I. 510.

16. The parties are also entering into stipulations regarding admissibility of certain exhibits, which when filed shall be incorporated fully herein by reference.

17. Each party may use an exhibit that is listed on the other side's exhibit list, to the same effect as though it were listed on its own side's exhibit list, subject to any evidentiary objections. Any exhibit, once admitted, may be used equally by any party subject to any limitations as to its admission into evidence. The listing of a document on a side's exhibit list is not an admission that such document is relevant or admissible when offered by the opposing side for the purpose that the opposing side wishes to enter the document into evidence. The fact that an exhibit is listed on a side's exhibit list does not mean that side believes the exhibit would be admissible if

offered by the other side. If a party attempts to introduce an exhibit listed only on the other side's exhibit list, the listing side reserves the right to object to such introduction, and they need not list objections to their own exhibits as part of the Pretrial Order. In addition, each party reserves the right to make objections under Federal Rules of Evidence 104, 105, 602, and 802 to any evidence offered by the other side, at the time such evidence is offered, in view of the specific context in which such evidence is offered.

18. Any date listed on an exhibit list is provided for convenience only and is neither evidence nor an admission of the date of the document, and failing to list a date on an exhibit list is neither evidence nor an admission of whether the document is dated.

19. Legible photocopies of United States patents and their corresponding applications and file histories may be offered and received into evidence in lieu of certified copies thereof, subject to all other objections which may be made to the admissibility of certified copies.

20. Unless a genuine question is raised as to the authenticity of the original, or in circumstances it would be unfair to admit the copy in lieu of the original, a duplicate of any document or photograph may be marked for identification, and, if otherwise admissible, offered and received into evidence with the same force and effect as the original, subject to any and all objections as could be made to the original, and on condition that the original of any such duplicate, if within custody or control of the offering party, be available for inspection at the trial by 7:00 pm two days before such duplicate is first used.

21. The parties agree that documents produced during the discovery phase by the parties or from third parties under subpoena during the discovery phase of this litigation and identified in **Exhibits 7, 8, or 9** to this Order are presumed *prima facie* genuine and authentic as

set forth in the parties' stipulation (D.I. 510). Nothing, however, shall prohibit a party from offering evidence to rebut the presumption.

22. Documents with writing in a language other than English must include a translation, which translation must be provided as part of the pretrial exchanges to the extent possible, but no later than **2:00 p.m.**[1] on the Monday before the first day of trial (i.e. December 9, 2024), and all supplemental translations must be received by that time. The Exhibit list shall include a column indicating which documents are foreign language and include translations. Objections to the form or substance of translations must be made one week before trial begins for all translations exchanged as part of the parties' pretrial exhibit exchange prior to December 3, 2024. Insofar as any supplemental translation exhibits are added, objections to the form or substance of translations must be made within two (2) days of the date the translation is provided and added to the exhibit list.

23. This Order contains the parties' good faith efforts to identify the universe of exhibits to be used in any party's case. The parties agree to forego exhibit objections prior to the submission of the Pretrial Order while reserving the right to make objections to any exhibits in accordance with the provisions specified herein including objection to exhibits listed on the parties Joint Exhibit List (**Exhibit 9**). To the extent supplemental exhibits are identified, the parties agree to disclose any supplemental exhibits promptly after identification. Reasonable supplementation of exhibit lists will be permitted until **2:00 p.m.** on the Monday before the first day of trial (i.e. December 9, 2024), and all supplemental exhibits must be received by that time. After that time, further supplementation shall only be permitted by agreement of the parties, with good cause shown, or with leave of the Court. Objections to the supplemental exhibits shall be due no later

[1] All times are listed in Eastern Daylight Time.

than 7:00 p.m. the night before the first day of trial. The parties reserve the right to offer additional exhibits for impeachment. Subject to other provisions of this Order, no party shall be permitted to offer as evidence any exhibit not present on an exhibit list absent good cause shown or by agreement of the parties, except that documents, deposition transcripts, or portions thereof, or other items, not specifically identified herein or offered into evidence, may be used at trial for purposes of impeachment or rehabilitation, if otherwise competent for such purposes. Exhibits not specifically included in Exhibits 7, 8, or 9 may not be used for rebuttal or reply purposes.

24. Unless otherwise stipulated among the parties, no exhibit will be admitted unless offered into evidence through a witness, who must at least be shown the exhibit. Exhibits may not be published, displayed, or otherwise shown to the jury until after evidentiary objections to an exhibit have been resolved by the Court. Once any objections are resolved, counsel may publish exhibits to the jury without requesting to do so. This includes publishing, displaying, or otherwise showing such exhibits to the jury prior to their admission into evidence according to the following procedure. By **7:30 p.m.** on a trial day, the parties will exchange lists of exhibits that were used that day. Disputes on the list (which will not include evidentiary objections, those having been resolved before the exhibit was published to the jury) will be provided no later than **9:00 p.m.** that day. The parties will meet and confer on the disputes by **10:00 p.m.** The following morning no later than **8:30 a.m.**, the parties will provide a list to the Court of the agreed-upon exhibits to be formally entered into evidence. Once admitted, counsel may publish exhibits to the jury without requesting to do so.

25. Provided they are not otherwise objected to, exhibits may be entered through expert witnesses.

26. Exhibits not objected to will be received into evidence without the need for additional foundation testimony, provided they are shown to a witness and moved into evidence as provided above.

27. A party will identify exhibits to be used in connection with examination of a witness by **7:30 p.m**. two nights before their intended use, and objections will be provided no later than **7:30 p.m.** one night before their intended use. The parties shall then meet and confer on the objections by **10:00 p.m.** one night before their intended use. This provision does not apply to demonstratives created during testimony, or demonstratives, documents, or other materials to be used for cross-examination, none of which need to be provided to the other side in advance of their use. In addition, blow-ups or highlights of exhibits or parts of exhibits or testimony are not required to be provided to the other side in advance of their use.

28. If good faith efforts to resolve the objections fail, the party objecting to the exhibits shall bring its objections to the Court's attention in the morning prior to the witness being called to the stand according to the procedures *infra* §XVI.E. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of objection to the exhibit.

29. Statements from any responses to requests for admission or interrogatories, or from pleadings or admitted facts from dispositive briefing in this litigation may be read at trial, provided the complete question and answer are read. The parties agree pleadings and discovery responses need not be included on the exhibit list and are not evidence. The party planning to use such a document in its case-in-chief agrees to provide a copy of the document it intends to use in Court to the other side and identify the portions it intends to use by no later than **7:30 p.m.** two days before it will be used in Court. The other side will provide objections thereto by **9:00 p.m.** that

same night, and the parties shall meet and confer by **10:00 p.m.** that same night to resolve such objections.

30. On or before the first day of trial, counsel will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list for each party.

B. Demonstratives

31. The parties' demonstratives to be used at trial need not be included on their respective lists of trial exhibits to be filed with the Court. Nippon Shinyaku's and/or NS Pharma's demonstratives will be identified with **PDX** numbers. Sarepta and/or UWA's demonstratives will be identified with **DDX** numbers. Demonstratives will be exchanged by the parties pursuant to the schedule below.

32. The parties will exchange demonstratives and a list of exhibits that they intend to use in their opening statements by **2:00 p.m.** the day before opening statements are made. The parties will provide any objections to such demonstratives and exhibits by **5:00 pm** the night before opening statements are made. The parties shall meet and confer about any objections by no later than **7:00 p.m.** that night. The parties agree that any changes to these materials made after **2:00 p.m.** the day before opening statements are made will be non-substantive (e.g., edits to font, layout, format, or to correct typographical errors) unless made in response to and for the purpose of resolving an objection.

33. Demonstratives to be used on direct examination of a witness will be exchanged pursuant to the procedures set forth below. These provisions do not apply to demonstratives created during testimony or demonstratives to be used for cross-examination, neither of which need to be provided to the other side in advance of their use. The parties also are not required to identify demonstrative exhibits previously used with a witness during trial. In addition, blow-ups or highlights of exhibits or parts of exhibits or testimony that are not included within a

demonstrative and used live during a witness's testimony, and which contain no additional markings, commentary, or alterations, are not required to be provided to the other side in advance of their use. In the event blow-ups, enlargements, highlights, or call outs of exhibits or testimony include, are coupled with, or presented alongside any characterizations, labels, or the like, the below provisions regarding exchange apply.

34. A party will provide demonstratives to be used in connection with direct examination of a witness by **7:30 p.m.** the night before their intended use, with an agreement that any changes to the demonstratives made after such exchange will be only font/layout/format/to correct typographical errors and not edits of substance, unless made in response to and for the purpose of resolving an objection. Objections will be provided not later than **9:00 p.m.** the night before their intended use. The parties shall then meet and confer on the objections by **10:00 p.m.** If any of the demonstratives change after the deadline, the party intending to use the demonstrative will promptly notify the opposing side of the change(s).

35. If good faith efforts to resolve objections to demonstrative exhibits fail, the objecting party shall bring its objections to the Court's attention prior to the opening statements or prior to the applicable witness being called to the witness stand according to the procedures *infra* §XVI.E. Failure to comply with these procedures, absent an agreement by the parties or approval by the Court, will result in waiver of the use of a demonstrative or waiver of objection to the demonstrative. Nothing in the foregoing is a waiver of any objection to the testimony of a witness in connection with the demonstrative.

36. A party seeking to use a demonstrative will provide a color representation of the demonstrative to the other side in PDF or other electronic form labeled with the exhibit or demonstrative number. Any video demonstrative shall be exchanged in a manner sufficient to

permit the opposing side to see the moving images and hear any included audio. Exchange of large boards is not required, and these demonstratives may be exchanged in 8½" x 11" format with the PDF/electronic exhibits being exchanged at that same time. In addition, blow-ups or highlights of exhibits or parts of exhibits or testimony that are not included within a demonstrative and used live during a witness's testimony, and which contain no additional markings, commentary, or alterations, are not required to be provided to the other side in advance of their use.

37. Demonstrative exhibits need not be included in the sides' respective exhibit lists. Reasonable, non-substantive edits or corrections of typographical and similar errors to demonstrative exhibits may be made to such exhibits before use.

38. The parties need not exchange demonstratives to be used in closing arguments.

39. By the later of either **6:00 p.m.** or **two hours after Court adjourns** two days before the side that is presenting their case-in-chief expects to rest, the resting side shall provide to counsel for the other party an estimate of when it expects to rest so that the sides have an opportunity to comply with the other notice provisions of this Order. To the extent that the deadline is extended beyond 6:00 p.m., the deadline for the parties to disclose the identity of witnesses to testify and the exhibits about which those witnesses intend to testify will be extended by the same amount of time.

40. Three days before the first day of trial the parties shall make available for inspection any physical exhibits to be used at trial, labeled with an exhibit number, whether such physical exhibits will be admitted into evidence or used as demonstratives. For purposes of clarity, such physical exhibits do not include document trial exhibits or graphical demonstratives, which are subject to the disclosure provisions above.

VI. WITNESSES

41. Nippon Shinyaku's and NS Pharma's witnesses that may be called to testify at trial are identified in the attached **Exhibit 10**. Nippon Shinyaku and NS Pharma reserve the right to call witnesses identified by Sarepta and/or UWA or additional witnesses for impeachment or rebuttal or to authenticate documents.

42. Sarepta's and UWA's witnesses that may be called to testify at trial are identified in the attached **Exhibit 11**. Sarepta and UWA reserve the right to call witnesses identified by Nippon Shinyaku and/or NS Pharma or additional witnesses for impeachment or rebuttal or to authenticate documents.

43. The listing of a witness on a side's witness list does not require the side to call that witness to testify and does not imply or establish that the listing side has the power to compel the live testimony of that witness or make that witness available to the opposing side. Any witness not listed will be precluded from testifying, absent good cause shown.

44. Each side may call a given fact witness only once during the jury trial, either live or by deposition. The parties recognize that certain fact witnesses may also testify during the bench trial on inequitable conduct. A party may go beyond the scope of their case-in-chief during direct examination of their fact witnesses and opposing counsel may go beyond the scope of the direct in their cross-examinations. Neither side will call a witness on the opposing side's witnesses list adversely. To the extent that a side does not call a will call witness that it has identified in its case in chief, the other side will have the ability to call that witness when it next has the floor and/or use the deposition testimony of that witness.

45. Nippon Shinyaku's and NS Pharma's list of deposition designations is attached as **Exhibit 12**. Also included in **Exhibit 12** are Sarepta's and UWA's objections and counter-designations to the testimony offered by Nippon Shinyaku and NS Pharma and Nippon Shinyaku's

and NS Pharma's objections to Sarepta's and UWA's counter designations. The parties agreed to provide any objections to counter designations and any counter-counter designations as part of the designation exchanges described below. Nippon Shinyaku and NS Pharma reserve the right to add deposition designations for witnesses that Sarepta and UWA do not bring live.

46. Sarepta and UWA's list of deposition designations is attached as **Exhibit 13**. Also included in **Exhibit 13** are Nippon Shinyaku's and NS Pharma's objections and counter-designations to the testimony offered by Sarepta and UWA and Sarepta's and UWA's objections to Nippon Shinyaku's and NS Pharma's counter-designations. The sides agreed to provide any objections to counter designations and any counter-counter designations as part of the designation exchanges described below. Sarepta and UWA reserve the right to add deposition designations for witnesses that Nippon Shinyaku and NS Pharma do not bring live.

47. These designations cover witnesses the parties anticipate may testify via deposition. Provision of deposition designations does not preclude the right of either party to call any listed witness live, subject to the disclosure provisions of the form of witness testimony outlined herein.

48. Any witness not listed on **Exhibits 10-13** will be precluded from testifying, absent good cause shown.

49. No party shall be required to present live testimony from any witness on its side's list of live witnesses.

50. Each party reserves the right to object to the relevance or admissibility of any evidence offered by another party at the time such evidence is offered and in view of the specific context in which such evidence is offered, only if that objection could not have been made timely as part of the Pretrial Order submissions because such context was not made available to the objecting party at the time. The parties are not required to designate deposition testimony to be

used for impeachment. In the event that a party or side cannot or does not call any designated "will call" live witness to trial, the other side may identify additional designations to which the other party or side may object and offer counter designations. All objections and colloquy of counsel and/or interpreters will be eliminated from the deposition designations when the designations are read to or viewed by the jury.

51. Each side will provide the other with an updated good-faith list of witnesses it intends to call live at the trial by one week before the first day of trial **by 7:00 p.m.**, without prejudice to the right to remove any such witness. Except as set forth herein, no fact or expert witness called by a side shall be permitted to testify in its case-in-chief, responsive, or rebuttal case at trial if not identified in this Order (including exhibits thereto), unless the Court determines that good cause exists for calling an unlisted witness. As discussed *infra* §XVI.B., Sarepta and UWA specifically object to Nippon Shinyaku/NS Pharma's disclosure of Donald Foy, and maintain that Mr. Foy should not be permitted to testify at trial, despite his inclusion on Nippon Shinyaku and NS Pharma's witness list as part of this Amended Order. The listing of a witness on a side's witness list or inclusion of witness's deposition testimony on a party's list of deposition designations does not require the party to call that witness to testify live or by designation, and does not imply or establish the listed party has the power to compel the live testimony of that witness or make that witness available to the opposing party.

52. Once a side has identified a witness on its final list, if the side later elects not to call that witness, it must make a good faith effort to make that witness available to be called by the other side, if the other side so chooses. The other side may also elect to designate deposition testimony from the witness.

53. Each side will provide the other side with a list, in order of presentation, of witnesses it intends to call live on direct examination by **7:30 p.m.** two days before those witnesses are intended to testify in Court. (For example, if a side intends to call a witness on Wednesday, that side shall disclose that witness's name to the opposing side no later than **7:30 p.m.** on Monday.) This list must also include those witnesses who are to be called by designation (whose designations will have been previously disclosed pursuant to the procedures described below), so as to disclose the order in which any witnesses called by designation shall appear. This list is the anticipated order of the presentation of witnesses, but if there will be adjustment to the order for that particular day, the other side must be timely informed. Any objections shall be provided by **9:00 p.m.** two days before the witness is to be called. No deviations from this notice shall be permitted except by agreement of the parties or for good cause shown. The parties shall meet and confer by **10:00 p.m.** two days before the witness is to be called to resolve any disputes, and if the objections to the disputed testimony are not resolved by the parties' meet and confer, they will be presented to the Court according to the procedures *infra* §XVI.E.

54. A live witness must testify in the same language in which that witness testified at deposition. For all of its witnesses who appear on the will call witness list who testified in Japanese at their depositions, Nippon Shinyaku and NS Pharma provide notice via this Order that such witnesses who appear live at trial will testify only in Japanese and use an interpreter. **[Sarepta's Proposal**:[2] The parties will meet and confer to agree on a mutually acceptable interpreter. The

[2] Sarepta's Position: Sarepta objects to Nippon Shinyaku/NS Pharma's plan to have *ex parte* discussions with its proposed interpreter, including having the interpreter participate in its witness preparation sessions and exposing the interpreter to privileged communications with the witness before the witness takes the stand. Sarepta contends that the interpreter should be agreed between the parties (ensuring an interpreter with a sufficient technical background is chosen) and should not have *ex parte* communications with the parties prior to or during trial.

interpreter agreed upon by the parties shall have no *ex parte* communications with the parties. Neither party intends to use a check interpreter.**]** **[Nippon Shinyaku/NS Pharma's Proposal**[3]: Nippon Shinyaku/NS Pharma will provide an interpreter to attend trial during its witnesses who will be testifying in Japanese. Sarepta and UWA shall be permitted to have a check interpreter in attendance. The parties agree that an interpreter shall not have *ex parte* communications with a witness once the witness is on the stand.**]** With the exception of expert witnesses and a corporate representative for each party, the parties agree that fact witnesses should be prevented from hearing the testimony of other witnesses pursuant to Federal Rules of Evidence 615. Fact witnesses, however, may be present for the parties' opening statements. Excluded witnesses will be

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Exposure to *ex parte* and/or privileged communications will—even inadvertently—bias the interpreter's choice of language in favor of NS's theories of the case. *See Advanced Tech. Incubator, Inc. v. Sharp Corp.*, 701 F. Supp. 2d 861, 862-63 (E.D. Tex. 2010) (disqualifying defendant's interpreter at trial for the appearance of impropriety arising from translating privileged conversations preparing defendant's witnesses for deposition). Unlike witnesses, interpreters are not subject to cross-examination. Further, it is prejudicial in that the interpreter will have familiarity with Nippon Shinyaku/NS Pharma's questions and the witness's answers during direct, and will be able to translate those questions and answers more quickly than they will be able to translate Sarepta's and/or UWA's cross examination questions. The *Taiho* Pretrial Order Nippon Shinyaku/NS Pharma cites below is irrelevant and off point. That document was the parties' [Proposed] Pretrial Order, and indicates that the parties agreed on the interpretation process. Here, the parties disagree.

[3] Nippon Shinyaku/NS Pharma's Position: Nippon Shinyaku/NS Pharma propose that interpreters be treated like witnesses and unable to have *ex parte* communications once the interpreter is interpreting a witness's testimony. Given the highly technical nature of testimony anticipated to be presented from witnesses whose native language is Japanese, Nippon Shinyaku/NS Pharma believe is both practical and fair to enable the interpreter—who will be under an oath to interpret accurately—to be exposed to and aware of the technical terms and related information for a witness's testimony. This will only serve to ensure the interpretation is most accurate and avoid needless delays with interpreters needing to pose questions on meaning of technical terms, as occurred during depositions in this case. The interpretation will also be subject to Sarepta's check interpreter to ensure it is fair and accurate. Nippon Shinyaku/NS Pharma's proposal is consistent with how this Court has handled witnesses testifying in other languages with the assistance of an interpreter in a recent trial. *See Taiho Pharma. Co. v. Eugia Pharma Specialties Ltd.*, C.A. No. 19-2309-JLH (D. Del.), Public Version of Pretrial Order (D.I. 173), ¶ 68.

prohibited from learning about, obtaining, or being provided with trial testimony of other witnesses. Counsel for the parties shall notify one another by e-mail of their corporate representative no less than two days before the first day of trial by **7:30 p.m**.

55. The parties may offer some or all the deposition testimony set forth in their side's designations, in **Exhibits 12 & 13**, during trial, so long as the party seeking to proffer the testimony has made a showing that witness is unavailable as that term is defined under the Federal Rules. If a party decides to offer less than all the designated testimony for a witness at trial, the opposing side may use such dropped testimony as counter-designations. A party's decision not to introduce some or all the testimony of a witness designated herein shall not be commented on at trial.

56. Any deposition testimony may be used at trial for the purpose of impeachment, regardless of whether a party identified that testimony on its list of deposition designations, if the testimony is otherwise appropriate for such purpose.

57. All irrelevant and redundant material, including colloquy between counsel and objections, will be eliminated when the deposition is read or viewed at trial. The manner of using counter-designations at trial shall be in the same manner (video versus read transcripts) as that used for the designation sought to be rebutted, such that all designations and counter-designations will be played or read to the jury, as the case may be, as one consecutive segment in the order the testimony appears in the transcript. If a party offers video testimony, that party shall be responsible for including video portions of counter-designated testimony that is designated as described in this section. If a party does not offer video testimony, that party need not offer video of the other side's counter-designations. The party who originally designated the testimony may elect whether it will

be played or read. **[Nippon Shinyaku/NS Pharma's Proposal**:[4] Insofar as video deposition testimony from a witness who testified in a language other than English is played, the entirety of the witnesses' testimony (including the responses provided in Japanese) shall be played to the jury so that the jury can accurately judge witness credibility. Insofar as deposition testimony from such witnesses is read, no party need to read a response provided in Japanese. The time for playing deposition testimony, including the non-English portion, will be charged to the party offering the testimony] [**Sarepta's Proposal**:[5] If a translator was used in a deposition, only portions of the testimony in English (whether original or translated) may be played or read. To the extent the Court allows or requires the entirety of a witness's testimony (including responses provided in Japanese) to be played to the jury, the time for playing all non-English portions of such testimony should be charged to the party requesting that such non-English portions be played, here Nippon Shinyaku/NS Pharma**]**. Regardless of whether deposition testimony is read or played by video, the time for each side's designated portions will be charged to the designating side.

[4] Nippon Shinyaku/NS Pharma's Position: Permitting deposition testimony to include the deponent's response provided in the deponent's native language before playing the English interpreted version read by an interpreter is consistent with how another court has handled the issue of interpreted deposition testimony during trial. *See Ushijima v. Samsung Elec. Co.*, 2015 WL 5173975 (W.D. Tex. Jan. 30, 2015), Joint Final Pretrial Order, ¶¶ 32-33.

[5] Sarepta's Position: Deposition testimony is difficult enough for juries to watch, and may be particularly difficult here, where the parties' interpreters at the depositions often engaged in lengthy colloquies in Japanese. Former Magistrate Judge Grewal rejected the precise argument Nippon Shinyaku/NS Pharma make here—that the non-English testimony must be viewed to assess credibility—holding that non-English testimony "may be edited out of the transcript/video clips for hearing/viewing by the jury." *Corning Optical Commc'ns Wireless Ltd. v. SOLiD, Inc.*, No. 5:14cv03750-PSG, 2015 WL 5569095, at *3 (N.D. Cal. Sept. 22, 2016); *see also* Pretrial Conference Tr. 43-45, *Corning Optical Commc'ns Wireless Ltd. v. SOLiD, Inc.*, D.I. 374 (N.D. Cal. Sept. 22, 2015) (Court rejecting counsel's argument that non-English testimony must be played "to evaluate the witness's credibility"). Sarepta further notes that the Joint Final Pretrial Order Nippon Shinyaku/NS Pharma rely on for support is inapposite because it appears the parties agreed to that provision. Here, the parties disagree.

58. Each side will provide the other with a list of final deposition designations (from the previously designated testimony) that it intends to introduce by **7:30 p.m.** three days before the date on which designations are intended to be used in court, and a statement of the manner in which the prior testimony should be presented (i.e. video versus read depositions). (For example, witnesses to be called by designation on Wednesday must be disclosed by **7:30 p.m.** the preceding Sunday, along with their proposed testimony.) The other side must identify any objections to the designated testimony and any counter designations no later than **7:30 p.m.** two days before the date on which the designations are intended to be used in court. The originally designating side may identify any objections or counter-counter designations by **8:30 p.m.** that day. All designations (but not counter-designations or counter-counter designations) must have been included in **Exhibits 12** and **13**, subject to the parties' reservation of rights set forth herein *supra* ¶¶ 44-45. The sides shall then meet and confer as to any objections and any disagreement regarding the manner in which testimony should be presented no later than **10:00 p.m**. that day. Any unresolved objections will be submitted to the Court in a joint submission by **8:30 a.m.** the next morning—i.e., one day before the date on which the designations are intended to be used in court. The joint submission shall include (i) a copy of the entire proposed testimony of the witness at issue, clearly highlighting the designations; and (ii) a cover letter identifying the pending objections, as well as a brief indication (no more than one sentence per objection) of the basis for objection and the offering side's response to the objection.

59. Either side may withdraw a designation at any time, particularly as the Court may resolve disputes about designated testimony on the day on which it is to be read or played. The sides will work together in good faith to ensure that both sides can adjust designations or counter-designations accordingly.

60. Failure to comply with these procedures, absent an agreement by the parties and approval of the Court, will result in waiver of the use of the testimony or waiver of objection to the use of the testimony.

61. When deposition designations are read or played at trial, each side will be charged for the time taken to read or play its designations, as measured by the proportion of lines of testimony for its designations to the total number of lines of testimony read, or by the actual time for video testimony if played, subject to the Court's resolution of the parties' dispute as to playing the entirety or only the English portions of such testimony discussed *supra* at ¶ 57.

62. For those witnesses whose prior deposition or trial testimony will be read or played to the jury, the parties shall be permitted to make brief transition statements to introduce the witnesses and their role in the litigation. However, counsel shall not be permitted to argue or comment on the evidence during transition statements.

VII. NIPPON SHINYAKU/NS PHARMA'S STATEMENT OF INTENDED PROOFS

63. Nippon Shinyaku's and NS Pharma's statement of intended proof at trial is limited to the issues for which Nippon Shinyaku and/or NS Pharma bears the burden of proof at trial and does not address the proof that Nippon Shinyaku and/or NS Pharma may choose to present in rebuttal to the defenses and counterclaims that Sarepta and UWA may present in their case-in-chief or in Nippon Shinyaku's and NS Pharma's rebuttal case.

64. Nippon Shinyaku's and NS Pharma's statement is based upon the current status of the case and the Court's current rulings. Nippon Shinyaku and NS Pharma reserves the right to revise this statement based on Sarepta's and UWA's statement of intended proof or any further decisions or orders of the Court. Nippon Shinyaku and NS Pharma incorporates by reference their statements of contested facts and issues of law in **Exhibits 3 and 5**, respectively. The following statements are not exhaustive, and Nippon Shinyaku and NS Pharma reserve the right to prove any

matters identified in their pleadings, infringement contentions, non-infringement contentions, validity contentions, invalidity contentions, interrogatory responses, and/or expert reports.

65. At trial, Nippon Shinyaku and/or NS Pharma intends to establish, through its presentation of evidence,[6] that:

a. Sarepta's infringement of the NS Patents was willful.

b. The Wilton Patents are invalid as further explained in Nippon Shinyaku's and NS Pharma's statements of contested facts and law.

c. The Wilton Patents are unenforceable due to inequitable conduct.

d. Nippon Shinyaku is entitled to damages in an amount adequate to compensate it for Sarepta's infringement, including without limitation no less than a reasonable royalty and/or lost profits.

e. Nippon Shinyaku is entitled to an accounting for acts of infringement prior to the date judgment is entered, to the extent such damages for such infringement are not reflected in the verdict.

f. Nippon Shinyaku is entitled to enhanced damages.

g. Nippon Shinyaku is entitled to pre- and post-judgment interest of any damages award.

h. Nippon Shinyaku is entitled to an award of attorneys' fees incurred in this litigation.

i. Nippon Shinyaku is entitled to an award of costs and other such relief in law or equity as the Court deems just and proper.

[6] Because the Court accepted Sarepta's stipulation of infringement and granted summary judgment of infringement (D.I. 544), Nippon Shinyaku/NS Pharma no longer need address infringement of the NS Patents at trial.

j. Sarepta and UWA are not entitled to any relief on their counterclaims.

VIII. SAREPTA AND UWA'S STATEMENT OF INTENDED PROOFS

66. Sarepta's and UWA's statement of intended proof at trial is limited to the issues for which Sarepta and UWA bear the burden of proof at trial and does not address the proof that Sarepta and UWA may choose to present in rebuttal to the defenses and counterclaims that Nippon Shinyaku and NS Pharma may present in its case-in-chief or in Sarepta's and UWA's rebuttal case.

67. Sarepta's and UWA's statement is based upon the current status of the case and the Court's current rulings. Sarepta and UWA reserve the right to revise this statement based on Nippon Shinyaku's and/or NS Pharma's statement of intended proof or any further decisions or orders of the Court. Sarepta and UWA incorporate by reference their statements of contested facts and issues of law in **Exhibits 4 and 6**, respectively. The following statements are not exhaustive, and Sarepta and UWA reserve the right to prove any matters identified in their pleadings, infringement contentions, non-infringement contentions, validity contentions, invalidity contentions, interrogatory responses, and/or expert reports.

68. At trial, Sarepta[7] and/or UWA intend to establish, through their presentation of evidence,[8] that:

a. Nippon Shinyaku's and NS Pharma's infringement of the Wilton Patents was and is willful.

b. The NS Patents are invalid as further explained in Sarepta's and UWA's statements of contested facts and law.

[7] Sarepta stipulates and agrees that Counterclaim V for Nippon Shinyaku's breach of the MCA (*see* D.I. 328) shall be dismissed with prejudice.

[8] Because the Court has now held that Nippon Shinyaku and NS Pharma infringe the Asserted Claim of the Wilton Patent (D.I. 541), Sarepta and UWA no longer need address infringement of the Wilton Patent at trial.

c. Sarepta and UWA are entitled to damages in an amount adequate to compensate it for Nippon Shinyaku's and NS Pharma's infringement, including without limitation no less than a reasonable royalty and/or lost profits.

d. Sarepta and UWA are entitled to an accounting for acts of infringement prior to the date judgment is entered, to the extent such damages for such infringement are not reflected in the verdict.

e. Sarepta and UWA are entitled to enhanced damages.

f. Sarepta and UWA are entitled to pre- and post-judgment interest of any damages award.

g. Sarepta and UWA are entitled to an award of attorneys' fees incurred in this litigation.

h. Sarepta and UWA are entitled to an award of costs and other such relief in law or equity as the Court deems just and proper.

i. Nippon Shinyaku and NS Pharma are not entitled to any relief on their counterclaims.

IX. DAMAGES

69. **Nippon Shinyaku and NS Pharma's Position:** At trial, Nippon Shinyaku will seek damages in the form of a reasonable royalty pursuant to 35 U.S.C. § 284 and also lost profits, as set forth in its expert reports, as compensation for Sarepta's past infringement, including induced and contributory infringement, and any continuing and future infringement of the NS Patents up until the date judgment is entered. Nippon Shinyaku will also seek an accounting for any infringement prior to the date judgment is entered, to the extent damages for such infringement are not reflected in the verdict. Nippon Shinyaku will also seek an ongoing royalty for any future infringement after the date judgment is entered. Nippon Shinyaku will further seek enhanced

damages under 35 U.S.C. § 284 for Defendant's willful infringement, a post-trial accounting of damages, an award of prejudgment and post-judgment interest, an award of attorneys' fees pursuant to 35 U.S.C. § 285, and interests, costs, and disbursements as justified under 35 U.S.C. § 284 and/or Federal Rule of Civil Procedure 54.

70. **Sarepta and UWA's Position:** At trial, Sarepta and UWA will seek damages in the form of a reasonable royalty pursuant to 35 U.S.C. § 284 and also lost profits, as set forth in its expert reports, as compensation for Nippon Shinyaku's and NS Pharma's past infringement, including induced and contributory infringement, and any continuing and future infringement of the Wilton Patents up until the date judgment is entered. Sarepta and UWA will also seek an accounting for any infringement prior to the date judgment is entered, to the extent damages for such infringement are not reflected in the verdict. Sarepta and UWA will also seek an ongoing royalty for any future infringement after the date judgment is entered, subject to further proceedings following the trial. Sarepta and UWA will further seek enhanced damages under 35 U.S.C. § 284 for Nippon Shinyaku's and NS Pharma's willful infringement, a post-trial accounting of damages, an award of prejudgment and post-judgment interest, an award of attorneys' fees pursuant to 35 U.S.C. § 285, and interests, costs, and disbursements as justified under 35 U.S.C. § 284 and/or Federal Rule of Civil Procedure 54.

X. MOTIONS *IN LIMINE*

71. Nippon Shinyaku and NS Pharma's motion *in limine* No. 1, and Sarepta and UWA's opposition thereto and Nippon Shinyaku and NS Pharma's reply, were attached as **Exhibit 14A** to the May 2024 Proposed Joint Pretrial Order. It can be found at D.I. 536-15 (under seal) and D.I. 590-15 (public). The Court denied this motion, stating it would consider a jury instruction if Nippon Shinyaku and NS Pharma proposed one to Sarepta and UWA at the time the evidence is

brought in or if there is a final jury instruction that Nippon Shinyaku and NS Pharma want to propose. D.I. 570 at 11:16-25.

72. Nippon Shinyaku and NS Pharma's three-part motion *in limine* No. 2, and Sarepta and UWA's opposition thereto and Nippon Shinyaku and NS Pharma's reply, were attached as **Exhibit 14B** to the May 2024 Proposed Joint Pretrial Order. It can be found at D.I. 536-16 (under seal) and D.I. 590-16 (public). The Court resolved motion 2A by obtaining the parties' agreement that Sarepta and UWA would only present evidence at trial consistent with the non-privileged evidence produced during discovery. D.I. 570 at 13:1-14:15. The Court denied motion 2B without prejudice to re-raising the issue if Dr. Dowdy decides to opine on someone's intent. D.I. 570 at 18:8-12. The Court denied motion 2C without prejudice to re-raise the issue if certain fact witnesses testified beyond what they stated they knew at their depositions. D.I. 570 at 20:2-5.

73. Nippon Shinyaku and NS Pharma's motion *in limine* No. 3, and Sarepta and UWA's opposition thereto and Nippon Shinyaku's and NS Pharma's reply, were attached as **Exhibit 14C** to the May 2024 Proposed Joint Pretrial Order. It can be found at D.I. 536-17 (under seal) and D.I. 590-17 (public). To resolve this dispute, the Court ordered the parties to work on language that can be read to the jury. D.I. 570 at 34:4-35:10. As discussed *infra* §XVI.A., the parties have been unable to reach agreement on this language and are seeking the Court's assistance in resolving this dispute.

74. Sarepta and UWA's motion *in limine* No. 1, and Nippon Shinyaku and NS Pharma's opposition thereto and Sarepta and UWA's reply, were attached as **Exhibit 15A** to the May 2024 Proposed Joint Pretrial Order. It can be found at D.I. 536-18 (under seal) and D.I. 590-18 (public). The Court requested, and Sarepta and UWA subsequently submitted a letter, identifying specific references in expert reports Sarepta and UWA were seeking to exclude. D.I.

570 at 46:6-11; D.I. 565. In addition to the paragraphs identified in that letter, Sarepta identifies the following paragraphs from Nippon Shinyaku and NS Pharma's subsequently served supplemental expert reports that it seeks to exclude: Hastings Supp. Op. Rpt. (dated July 3, 2024) ¶¶ 87, 90, 99, 100, 104-108, 117, 125, 133, 186, 187 available at D.I. 604-06; Hastings Supp. Reply Rpt. (dated Sept. 4, 2024) ¶¶ 51-59, 94 available at D.I. 612-1, Ex. 17 (excerpts); and Wood Supp. Reply Rpt. (dated Sept. 4, 2024) ¶¶ 12-15 available at D.I. 612-1, Ex. 6. The Court took the parties' submissions on this motion under advisement, but did not issue a ruling. D.I. 570 at 49:7-10. As discussed *infra* §XVI.A., the parties' dispute as to this motion has not been resolved and they respectfully request the Court's assistance in doing so.

75. Sarepta and UWA's motion *in limine* No. 2, and Nippon Shinyaku's and NS Pharma's opposition thereto and Sarepta's and UWA's reply, were attached as **Exhibit 15B** to the May 2024 Proposed Joint Pretrial Order. It can be found at D.I. 536-19 (under seal) and D.I. 590-19 (public). The Court granted this motion in part, noting that the contours of what can be said before the jury "is something you-all can work on." D.I. 570 at 54:10-56:24. As discussed *infra* §XVI.A., the parties dispute the scope of what may be said to the jury and respectfully request the Court's assistance in resolving the dispute.

76. Sarepta's and UWA's motion *in limine* No. 3, and Nippon Shinyaku's and NS Pharma's opposition thereto and Sarepta's and UWA's reply, were attached as **Exhibit 15C** to the May 2024 Proposed Joint Pretrial Order. It can be found at D.I. 536-20 (under seal) and D.I. 590-20 (public). In response to this motion, the Court advised the parties it was "considering whether to clarify and/or amend the Court's construction of 'base sequence' before the case goes to the jury." D.I. 561. Following the May 6, 2024 Pretrial Conference, the Court clarified the claim construction, resolving this dispute. D.I. 573.

XI. NUMBER OF JURORS

77. There shall be eight jurors. The Court will conduct jury selection through the "struck juror" method, beginning with the Court reading voir dire to the jury panel in the courtroom, continuing by meeting with jurors individually and addressing any challenges for cause, and concluding with peremptory strikes.

XII. NON-JURY TRIAL

78. The parties agree that certain issues in this case are issues for the Court to determine, specifically: (1) whether this case is an exceptional case, and if so, whether enhanced damages, attorneys' fees, and/or costs are warranted; and (2) whether the Wilton Patents are unenforceable for inequitable conduct.

XIII. LENGTH OF TRIAL

79. This matter is scheduled for jury selection on **December 13, 2024**, and a **5-day jury** trial beginning at **9:30 a.m.** on **December 16, 2024**, with the subsequent trial days beginning at **9:00 a.m.** Until the case is submitted to the jury for deliberations, the jury will be excused each day at **5:00 p.m.**

80. The trial will be timed. The Court has determined that each party will have 12.5 hours[9] allocated to their case presentation, including opening statements and closing arguments. Unless otherwise ordered, time will be charged to a side for its opening statement, direct and redirect examinations of witnesses it calls, cross-examination of witnesses called by any other party, and closing arguments. The Courtroom Deputy will keep a running total of trial time used

[9] Initially, the Court allocated 11 hours per side for trial. Apr. 18, 2024 Teleconference Tr. at 19:4-9. However, the Court later moved jury selection to the Friday proceeding trial (December 13, 2024), in order to "give a little more time" to the parties for trial. *See* May 9, 2024 Conference Tr. at 3:11-16; D.I. 597. Pursuant to this discussion, the parties have proposed 12.5 per side.

by counsel. If any side uses all of its allotted trial time, the Court will terminate that side's trial presentation.

81. The parties agree that the presentation of evidence will proceed as follows:

a. Opening Statements (Nippon Shinyaku and NS Pharma first, followed by Sarepta and UWA);

b. Nippon Shinyaku and NS Pharma's presentation of its case in chief on its asserted claims and counterclaims that are to be tried to the jury—namely, willfulness, patent damages, and invalidity of the Wilton Patent.

c. Sarepta's presentation of its case in chief on its asserted claims and counterclaims that are to be tried to the jury—namely, willfulness, patent damages, and invalidity of the NS Patents. Sarepta will also present evidence rebutting Nippon Shinyaku's presentation on its affirmative claims regarding willfulness and damages for the NS Patents. Sarepta and UWA will also present evidence rebutting Nippon Shinyaku and NS Pharma's presentation on invalidity of the Wilton Patent.

d. Nippon Shinyaku's and NS Pharma's presentation of evidence to rebut Sarepta's and UWA's presentation of willfulness and damages for the Wilton Patent and invalidity with respect to the NS Patents;

e. Closing arguments (Nippon Shinyaku and NS Pharma first, followed by Sarepta and UWA).

Consistent with the Court's order (D.I. 529), Nippon Shinyaku and NS Pharma will present their inequitable conduct and unenforceability cases to the Court in a bench trial held "simultaneously with the jury trial on the patent issues, with evidence pertaining solely to inequitable conduct being presented to the Court after the jury is released at the end of each day and/or while the jury is

deliberating." *Id.* The bench trial can be completed allocating **[Sarepta's Proposal:**[10] 2 hours to each party's presentation**] [Nippon Shinyaku/NS Pharma's Proposal:**[11] 2.5 hours to each party's presentation**]**. The parties shall present such evidence at the convenience of the Court. The parties recognize the Court's decision that "it can better and more efficiently address [issues regarding expert testimony pertaining to inequitable conduct under Rule 702] in context either during or after the bench trial," and its order that, should it conditionally admit disputed expert testimony subject to a later Rule 702 determination after the bench trial, the parties shall address such issues in the post-trial briefing. D.I. 545 at 2-3. The parties anticipate presenting the Court with brief opening statements during the bench trial portion of the case.

XIV. MOTIONS FOR JUDGMENT AS A MATTER OF LAW

82. The parties will make motions for judgment as a matter of law ("JMOL") orally at a subsequent break at the close of all evidence out of the presence of the jurors. The Court can then decide, based on the motions presented orally, whether to entertain argument or further briefing. The parties also agree that any renewed JMOL motions will be addressed in connection with the schedule for post-trial briefing to be set by the Court.

[10] Sarepta's Position: This adds a total of four hours of testimony and should be sufficient. This is particularly so given that since the May 2024 Proposed Pretrial Order was filed, two thirds of the issues to be addressed at the bench trial have been dropped or dismissed by stipulation. These issues are Sarepta's inequitable conduct claims against Nippon Shinyaku and Nippon Shinyaku's breach of contract claim.

[11] Nippon Shinyaku/NS Pharma's Position: Given the hotly contested factual nature of the bench trial portion of this case and the necessary witnesses to prove its case, Nippon Shinyaku and NS Pharma believes that 2.5 hours per side will allow both parties to fairly present their evidence. Nippon Shinyaku/NS Pharma's request for 2.5 hours per side is a significant reduction in time from the originally requested 4-hour bench trial.

XV. AMENDMENT OF THE PLEADINGS

83. The parties are not seeking any amendments to the pleadings, except as noted herein regarding:

- Nippon Shinyaku's dismissal with prejudice of its claims of infringement of the following NS Patent claims:
    - U.S. Patent No. 10,683,322, claims 1-4, 6-9 (Second Amended Complaint, Claim IX (D.I. 86); *see also* D.I. 498 (stipulating to partial dismissal with prejudice of remaining '322 patent claims);
    - '092 Patent, claims 1 and 2 (partial dismissal of Second Amended Complaint, Claim IV (D.I. 86)); '461 Patent, claim 1 (partial dismissal of Second Amended Complaint, Claim V (D.I. 86)); '217 Patent, claims 1-3 (partial dismissal of Second Amended Complaint, Claim VIII (D.I. 86)), '741 Patent, claims 1-2, 4-12 (partial dismissal of Second Amended Complaint, Claim VII (D.I. 86)); '106 Patent, claim 2 (partial dismissal of Second Amended Complaint, Claim VI (D.I. 86)); '361 Patent, claims 1-7 (dismissal of Second Amended Complaint, Claim III (D.I. 86); *see also* D.I. 498 (stipulating to "dismissal with prejudice of Claim III (Infringement of the '361 Patent)")).
- Sarepta's and UWA's dismissal with prejudice of their claims of infringement for the following Wilton Patent claims:
    - U.S. Patent No. 9,994,851, claim 2 (partial dismissal of Second Amended Answer, Defenses, and Counterclaims, Counterclaim I (D.I. 328));
    - U.S. Patent No. 10,227,590, claims 1-2 (Second Amended Answer, Defenses, and Counterclaims, Counterclaim II (D.I. 328)); and

- U.S. Patent No. 10,266,827, claims 1-2 (Second Amended Answer, Defenses, and Counterclaims, Counterclaim III (D.I. 328)).

- Nippon Shinyaku's partial dismissal with prejudice of its claim that the Wilton Patents are invalid under 35 U.S.C. § 103 (Second Amended Complaint, Claim II, ¶¶ 87-88 (D.I. 86)).
- Sarepta's dismissal with prejudice of its breach of contract counterclaim (D.I. 328, Counterclaim V).
- Sarepta's dismissal with prejudice of its inequitable conduct counterclaim (Second Amended Answer, Defenses, and Counterclaims, Counterclaim VI (D.I. 328)).

XVI. ADDITIONAL MATTERS

A. Open Issues Remaining After the May 6, 2024 Pretrial Conference

84. [**Sarepta's Proposal:**[12] As the jury will be tasked with assessing complicated technology and damages claims in a short, five-day trial, that the invalidity of the asserted claims

[12] Sarepta's Position: Nippon Shinyaku's continued assertion of five different NS Patents needlessly complicates the already complicated issues that the jury will be tasked with deciding in a very short time frame. All five NS Patents are in the same patent family, have the same effective filing date, and share a substantively identical specification. Moreover, Nippon Shinyaku does not assert that there is any substantive difference between the five asserted NS Patent claims that matters for assessing Sarepta's obviousness claim, or that the number of asserted claims or patents affects the amount of damages Nippon Shinyaku is seeking. Instead, all five asserted NS Patent claims are long recitations of substantively the same technical terms interspersed with pictures of chemical structures, about which there is no substantive dispute that would affect the obviousness analysis. Thus, the only possible reasons for Nippon Shinyaku's continued refusal to limit its claims are to (1) force Sarepta to use more of its trial time addressing the multiple, duplicative terms across for each of the five claims (something Nippon Shinyaku need not do, given that Sarepta stipulated to infringement) and (2) imply that Nippon Shinyaku has more patent rights than Sarepta or that because the patent office issued five patents on its technology, the patents would not have been obvious (which is untrue, since not only did the same examiner review all five patents, but Nippon Shinyaku also filed terminal disclaimers resulting in the examiner not issuing any additional prior art rejections of the later patents). These reasons are unfair, prejudicial, and will endanger the jury's verdict, given that the number of asserted patents is legally irrelevant to the obviousness analysis. What's more,

from all five NS Patents will stand or fall together, and that Nippon Shinyaku's claimed damages are independent of the number of patents or claims asserted, the Court further orders that Nippon Shinyaku is limited to asserting claims from only one NS Patent. Doing so will focus the issues for the jury, avoid confusion, and avoid a waste of time and resources, better allowing it to resolve the substantive disputes between the parties.**] [Nippon Shinyaku/NS Pharma's Proposal: N/A]**[13]

85. As discussed *supra* §X, a few open issues remain regarding the parties' motions *in limine* for which the parties request the Court's assistance.

86. Regarding Nippon Shinyaku's and NS Pharma's motion *in limine* No. 3, the Court ordered and the parties agreed to work on language regarding Sarepta's IPR filings as evidence of Sarepta's non-willfulness. D.I. 570 at 34:4-35:10. However, the parties have been unable to reach agreement on such language. [**Sarepta's Proposal:**[14] As such, the Court has decided that the jury

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it could lead to an inconsistent jury verdict necessitating a retrial, in the event that some but fewer than all patents are invalidated. In respect of the jury's and the Court's time and effort, Nippon Shinyaku should be ordered to limit its case to one asserted patent (just as Sarepta has done, despite having more) so the jury and the Court may focus on the substantive dispute between the parties.

[13] Nippon Shinyaku/NS Pharma's Position: The NS Patent claims are not identical, and the number of asserted patents and claims is not unreasonable. Sarepta has not identified any legal basis for limiting Nippon Shinyaku to a single patent and claim. As such, Nippon Shinyaku should not be further limited in the number of asserted patents and claims.

[14] Sarepta's Position: Sarepta's proposal tracks the Court's guidance at the May 2024 Pretrial Conference, providing evidence that Sarepta sought to challenge the NS Patents before NS brought suit and that its challenge was not frivolous because the patent office was willing to entertain it but did not do so for procedural reasons. *See* D.I. 570 at 32:8-15, 33:1-9. Nippon Shinyaku's and NS Pharma's proposal is potentially misleading in that the jury may infer that Sarepta's "attempt[] to challenge the patentability of the NS Patents" and the "order to withdraw that challenge" means that Sarepta's challenge was frivolous. Further, Nippon Shinyaku's and NS Pharma's proposal risks juror confusion over how the "order to withdraw that challenge" came about. Resolving this confusion would necessitate discussing IPRs—the very point the Court seeks to avoid—because it would involve discussing the parties' contract specifying the fora in which patentability disputes may be raised.

shall be informed that "Before NS filed this lawsuit, Sarepta challenged the validity of the NS patents through a process at the patent office. The patent office was willing to entertain Sarepta's challenge. However, for procedural reasons, it was determined that Sarepta's challenge to the validity of the NS patents had to be decided in this court rather than the patent office."**]. [Nippon Shinyaku/NS Pharma's Proposal:**[15] As such, the Court has decided that the jury shall be informed that "Before NS filed this lawsuit, Sarepta attempted to challenge the patentability of the NS Patents. Sarepta was ordered to withdraw that challenge and bring its arguments in this litigation."**].**

87. Regarding Sarepta and UWA's motion *in limine* No. 1, the Court took the parties' submissions on this motion under advisement, but did not issue a ruling. D.I. 570 at 49:7-10; *id*. at 35:11-49:10 (full argument). **[Sarepta's Proposal:** [16] As the Court recognized at the May 2024

[15] Nippon Shinyaku/NS Pharma's Position: Sarepta's proposal is factually inaccurate. The patent office did not dismiss Sarepta's IPRs due to "procedural reasons" but rather because the Federal Circuit ruled that Sarepta was in breach of contract and contractually prohibited from challenging the claims at the Patent Office, so Sarepta ordered to request dismissal. Should the Court adopt Sarepta's proposal, it would need to further clarify to the jury the nature of the contract, its provisions, and the complex procedural history, including that Sarepta was in breach of the parties MCA and was ordered by the Court to withdraw its challenges. Such an explanation is likely to confuse the jury. Nippon Shinyaku and NS Pharma's proposal is simpler and factually accurate.

[16] Sarepta's Position: Sarepta and UWA stand by their briefing and argument for their motion *in limine* No. 1. As Sarepta explained at the May 2024 Pretrial Conference, Nippon Shinyaku and NS Pharma want to rely on out-of-context statements involving patent applications and patents that are not those of the Wilton Patent-in-suit, have different priority dates and specifications, and claims of different scope. D.I. 35:22-36:7. Because of the potential for confusion, such statements from satellite proceedings are routinely excluded. *Sonos, Inc. v. D&M Holdings Inc.*, No. CV 14-1330-WCB, 2017 WL 5633204, at *1 (D. Del. Nov. 21, 2017). Contrary to Nippon Shinyaku and NS Pharma's assertion that Sarepta and UWA "chose to rely upon the '007 Interference to secure issuance of the now-asserted claim," only the decision from the Patent Trial and Appeal Board was discussed, not the materials that Nippon Shinyaku and NS Pharma now seek to introduce at trial. Further, many of the statements Nippon Shinyaku and NS Pharma characterize as "factual statements" are arguments made by

Pretrial Conference (D.I. 570 at 35:11-13), this motion seeks to exclude evidence or argument regarding other proceedings involving patents or applications that are not the patents-in-suit.**]** **[Nippon Shinyaku/NS Pharma's Proposal:** [17] This motion broadly seeks to exclude evidence from the Wilton Patent's intrinsic record, including statements made during its prosecution and a highly relevant interference proceeding regarding exon 53 skipping ASOs references to an interference proceeding, as well as Sarepta's prosecution statements made during its prosecution

attorneys in the context of different priority dates, different patent claims, and different disclosures. This will be a very fast, compressed trial given that patents are asserted in both directions, such that there will not be time to provide adequate context for the jury about these unrelated statements. As such, the better, less prejudicial approach would be to exclude these statements, which at best have only marginal relevance, so the jury can focus on the substantive disputes they will be tasked with resolving. Nippon Shinyaku and NS Pharma's new claim that Sarepta seeks to exclude material from the prosecution history of the Wilton Patent-in-suit is simply incorrect. The identified paragraphs include discussions of and citations to the satellite proceedings. That is what Sarepta has moved to exclude.

[17] Nippon Shinyaku/NS Pharma's Position**:** Sarepta is unfairly seeking to strike Nippon Shinyaku and NS Pharma's reliance on factual representations Sarepta and UWA repeatedly made to the Patent Office regarding (1) exon 53 skipping remaining "highly unpredictable" many years after UWA's alleged invention; and (2) the inventiveness of the claimed subject matter of the NS Patents (which Sarepta now claims is obvious). The vast majority of these statements (relating to the '007 Interference) are intrinsic evidence both because the '007 Interference is related '851 Patent because Sarepta and UWA specifically chose to rely upon the '007 Interference to secure issuance of the now-asserted claim. Moreover, Sarepta's request is overbroad and illustrates it is abandoning its prior affirmation that it would be "fine with [Nippon Shinyaku] citing a specific statement [] in the file history of the Wilton patent that's at suit." Pre-Trial Hr'g. Tr. (May 9, 2024) at 47:22-25; *see also id.* at 43:23-44:5 (argument by NS's counsel preceding this affirmation). Sarepta's supplemented list of paragraphs to strike also includes substantial amounts of analysis that predominantly analyzes the Wilton Patent's prosecution history and/or does not solely rely upon citation to the '007 Interference. *See, e.g.*¸ D.I. 604-06, Hastings Supp. Op. Rpt. (dated July 3, 2024) ¶¶ 87, 90, 117, 186-187 (citing the "Wood Interference Declaration" only in "see also" or string citations), 99, 106-108, 125 (only mentioning the '007 Interference in passing while primarily analyzing the '851 Patent's prosecution history and/or specification), 100 (analyzing only the '851 Patent's prosecution history), 125 ('007 Interference only mentioned in one sentence of n. 19); D.I. 612-1, Ex. 17, Hastings Supp. Reply Rpt. (dated Sept. 4, 2024) ¶¶ 51-55 (no discussion of the '007 Interference at all), 59 (discussing Sarepta's and UWA's reliance on the '007 Interference to argue for patentability in the '851 Patent's prosecution history), 94 (mentioning the '007 Interference only in passing).

of other claims directed at exon 53 skipping ASOs.**]** The parties' briefing can be found at D.I. 536-18 (under seal) and D.I. 590-18 (public). The argument at the May 2024 Pretrial Conference regarding this motion can be found at D.I. 570 at 35:11-49:10. The day after the conference, Sarepta submitted a letter identifying the specific paragraphs from the expert reports it was seeking to exclude. D.I. 565. In addition to the paragraphs identified in that letter, Sarepta identifies the following paragraphs from Nippon Shinyaku and NS Pharma's subsequently served supplemental expert reports that it seeks to exclude: Hastings Supp. Op. Rpt. (dated July 3, 2024) ¶¶ 87, 90, 99, 100, 104-108, 117, 125, 133, 186, 187 available at D.I. 604-06; Hastings Supp. Reply Rpt. (dated Sept. 4, 2024) ¶¶ 51-59, 94 available at D.I. 612-1, Ex. 17 (excerpts); and Wood Supp. Reply Rpt. (dated Sept. 4, 2024) ¶¶ 12-15 available at D.I. 612-1, Ex. 6 (excerpts).

88. **[Sarepta's Proposal:**[18] Regarding Sarepta and UWA's motion *in limine* No. 2, the Court largely granted this motion to exclude evidence and argument comparing the parties' commercial products, stating "we're going to hear something from NS's damages expert about ramp-up time. And none of that testimony should be discussing that our product is better or

[18] There is no dispute that, because there have been no head-to-head studies between the parties' products, comparing the efficacy of the two products (e.g., by comparing dystrophin levels from their respective labels) would be improper. While Nippon Shinyaku and NS Pharma have agreed not to make "direct" comparisons between the two products (whatever that means), it refuses to agree not to make indirect comparisons (e.g., by putting their reported dystrophin levels on consecutive slides or having their clinical expert say he (and others) would prescribe VILTEPSO over VYONDYS 53 based on an alleged higher total amount or alleged larger change from baseline of dystrophin protein reported in the products' labels). As discussed at the May Pretrial Conference, that would be akin to promising not to say one lawyer is taller than the other, but reserving the right to say that Mike is 6'3" whereas Jack is 5'10," or showing their heights side by side or on adjacent slides. If Nippon Shinyaku and NS Pharma are permitted to compare the efficacy of the two products—even indirectly—Sarepta would have no choice but to rebut that improper and inaccurate premise, e.g., by introducing Nippon Shinyaku and NS Pharma's recent clinical failures, leading to an unnecessary minitrial and juror confusion. There is a simple solution: removing the word "directly" from Sarepta's proposal, thus prohibiting any comparisons, whether direct or indirect. All the jury needs to know is that both products have been deemed safe and effective by the FDA.

anything like that." D.I. 570 at 56:7-24. After the May 2024 Pretrial Conference, Nippon Shinyaku and NS Pharma reported that its VILTEPSO clinical trial failed to show any statistically significant difference over placebo on its primary efficacy endpoint. *See* Press Release, "NS Pharma Shares Preliminary Results of Viltolarsen (NS-065 / NCNP-01) Phase 3 Clinical Trial (RACER53 Study)," *available at* https://www.nspharma.com/pdfs/[NSP]_Press_Release_RACER53_Study_Results.pdf (last visited Nov. 25, 2024). Given this development, the parties agree that, while the parties will be allowed to discuss the general efficacy of their products, they will not be allowed to criticize the other side's product(s).**] [Nippon Shinyaku/NS Pharma's Proposal[19]:** NS agreed that it would

[19] Sarepta's proposal that "while the parties will be allowed to discuss the general efficacy of their products, they will not be allowed to criticize the other side's product(s)" is vague and lacks clarity as to what information can be presented and trial. Sarepta's proposal should be rejected because it is unclear what exactly Sarepta proposes should be permitted or prohibited—indeed, the Court recognized this problem during the pretrial conference. D.I. 570 at 54:21-55:1 ("Maybe this is something you-all can work on. I don't want to preclude him from talking about what's in their label either, right, and have you say that they've broken the agreement. So maybe it just has to do with putting them all right next to each other on a split screen.").

However, Nippon Shinyaku believes that Sarepta's concerns are unfounded. Nippon Shinyaku has already agreed that it would not make direct comparisons or claim superiority based on the Phase II clinical trial dystrophin production numbers. Nippon Shinyaku does not intend to have Dr. Strober offer testimony at trial comparing the efficacy of VILTEPSO and VYONDYS 53. Instead, Dr. Strober will offer testimony separately describing the FDA approved labels of both VILTEPSO and VYONDYS 53, including that (i) identifying the approved indication of each product, and (ii) describing the clinical trial results set forth in each product label that were the basis of FDA approval—namely that the administration of each product resulted in a specific increase in measured dystrophin levels. To the extent that Sarepta seeks to exclude Dr. Strober from testifying about the individual increases in dystrophin levels reported on both parties' labels, Sarepta's proposal must be rejected. The dystrophin related data is provided in the prescribing information for each product as well as in other FDA-approved marketing materials, and is simply a fact in the record relating to these products. Sarepta's argument regarding height does not accurately reflect the situation. Sarepta claims that proposed testimony about the varying dystrophin levels is "akin to promising not to say one lawyer is taller than the other, but reserving the right to say that Mike is 6'3" whereas Jack is 5'10"." But this is not so, instead, Nippon Shinyaku has promised not to claim that one attorney's

not make direct comparisons or claim superiority based on the Phase II clinical trial dystrophin production numbers. However, the dystrophin related data that Sarepta seeks to exclude is provided in the prescribing information for each product as well as in other FDA-approved marketing materials. Precluding Nippon Shinyaku and NS Pharma from relying on the product labels generally is unnecessary given their agreement not to directly compare the data.**]**.

89. **[Sarepta's Proposal:**[20] Because both sides' breach of contract claims were either dropped or have been dismissed by stipulation following the May 2024 Pretrial Conference, the parties agree that, to avoid juror confusion and potential prejudice, neither side will mention, discuss, or otherwise refer to the breach of contract claims before the jury.**] [Nippon Shinyaku/NS Pharma's Proposal:**[21] As discussed above, the parties dispute the language that should be used to describe Sarepta's filing of IPRs against Nippon Shinyaku's patents at the PTAB and the Court's

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height is superior to the other's—simply describing Mike as 6'3" and Jack as 5'10" does not indicate any superiority of either height, it is a plain statement of facts. Similarly, Nippon Shinyaku should be permitted to identify and report the dystrophin level data used by the FDA to approve each product without comparing or claiming that either level of dystrophin production is superior. Therefore, precluding Nippon Shinyaku and NS Pharma from relying on the dystrophin information in the product labels is unnecessary given the agreement not to directly compare the data.

[20] Sarepta's position: Sarepta incorporates its position *supra* at ¶ 86 n.14. As noted there, if Nippon Shinyaku and NS Pharma's proposed language regarding Sarepta's IPR filings is adopted (it should not be), the parties will need to discuss what IPRs are and the Patent Trial and Appeal Board's decision to institute based on the merits of Sarepta's obviousness challenge—the very point the Court seeks to avoid—because it would involve discussing the parties' contract specifying the fora in which patentability disputes may be raised. Thus, Sarepta's position here is contingent on the Court's resolution of the parties' dispute *supra* at ¶ 86. To the extent that any evidence refers to the breach of contract issue, Sarepta will work with Nippon Shinyaku, NS Pharma, and the Court to prepare any necessary redactions or other appropriate measures.

[21] Nippon Shinyaku/NS Pharma's Position: Nippon Shinyaku and NS Pharma incorporate their position *supra* at ¶ 86 n.15. To the extent that the Court adopts Nippon Shinyaku and NS Pharma's proposed language regarding Sarepta's improper filing of its IPRs, there will be no need to describe any proceedings related to the IPRs or the breach of contract that caused the Federal Circuit and District Court to order their withdrawal.

order forcing them to withdraw those IPRs based on Sarepta's breach of an agreement between the parties. To the extent that Sarepta continues to describe the reasons for its withdrawal as "for procedural reasons," Nippon Shinyaku and NS Pharma should be permitted to explain that those "procedural reasons" resulted from Sarepta's breach of the MCA and subsequent order of the Court enjoining Sarepta from proceeding with them.

B. New Issues Raised After the May 6, 2024 Pretrial Conference

90. The parties have filed new motions since the last pre-trial conference that are still outstanding.

91. Nippon Shinyaku and NS Pharma's motion to preclude supplemental opinions of Dr. Steven Dowdy—related to his reliance on post-priority date art to support written description and enablement—and Sarepta's and UWA's opposition thereto and Nippon Shinyaku's and NS Pharma's reply, can be found at D.I. 613, D.I. 621, and D.I. 628 (under seal) and D.I. 620, D.I. 624, and D.I. 632 (public). The Court has not ruled on this motion.

92. Sarepta and UWA's motions to preclude 1) NS's Expert Opinions and Testimony Applying a New and Improper Construction of "Morpholino;" 2) Dr. Wood's Irrelevant and Unhelpful Opinions and Testimony; 3) Dr. Hastings's Opinions and Testimony Concerning Enablement of 5'- and 3'-End Modifications; and 4) Dr. Hastings's Opinions and Testimony Applying Incorrect Written Description Law are pending. Sarepta and UWA's motions, opening brief, and supporting declaration can be found at D.I. 611-612 (under seal) and D.I. 607-610 & 618-619 (public). Nippon Shinyaku and NS Pharma's opposition thereto can be found at D.I. 623 (under seal) and D.I. 626 (public). Sarepta and UWA's reply can be found at D.I. 627 (under seal) and D.I. 631 (public). The Court has yet to rule on these motions.

93. On October 30, 2024, Nippon Shinyaku and NS Pharma served an Amended Witness List identifying for the first time that it intended to bring Mr. Donald Foy to testify at trial.

Sarepta objects to Mr. Foy's testimony, as Nippon Shinyaku/NS Pharma did not disclose Mr. Foy on its Rule 26(a)(1) Initial Disclosures until November 8, 2024 and failed to show that Mr. Foy has personal knowledge of any relevant information. The parties positions on this dispute are as follows:

a. **Sarepta's Position:** Mr. Foy should not be permitted to testify. Upon receiving Nippon Shinyaku and NS Pharma's Amended Witness List, Sarepta notified Nippon Shinyaku and NS Pharma that it appeared that Mr. Foy does not have personal knowledge relevant to the case, given that his LinkedIn profile indicates that he only joined NS Pharma in 2023. Sarepta requested that Nippon Shinyaku and NS Pharma make Mr. Foy available for deposition (which they had not offered) and requested additional information to consider Nippon Shinyaku and NS Pharma's request. This information included the topics Mr. Foy intends to cover, the documents he intends to testify about, and the basis for Mr. Foy's personal knowledge about the same. Sarepta also requested that Nippon Shinyaku and NS Pharma immediately produce all relevant documents in Mr. Foy's possession, custody, or control. Despite repeated requests for this information, Nippon Shinyaku and NS Pharma never provided it. Instead, they initially offered Mr. Foy for a half-day deposition on November 20, 2024. Only after repeated exchanges did Nippon Shinyaku and NS Pharma 1) serve their Rule 26(a)(1) Initial Disclosures disclosing Mr. Foy and 2) finally agree to make him available for a full seven hour deposition on November 20, 2024.[22]

In the interest of narrowing the dispute for the Court, Sarepta took Mr. Foy's Rule 30(b)(1) deposition, which confirmed that Mr. Foy has no personal knowledge of facts or documents relevant to the case. Mr. Foy began working at NS Pharma in September 2023, after the July 2023

[22] Sarepta is happy to provide the parties' correspondence on this matter if the Court would find it helpful.

close of fact discovery in this case. Foy Dep. Tr. 19:12-20:13; D.I. 269. Mr. Foy testified that the source of his knowledge is what he has been told by others or Nippon Shinyaku/NS Pharma's counsel. For example, Mr. Foy testified that he first reviewed documents relating to the financial relationship between Nippon Shinyaku and NS Pharma relating to VILTEPSO "sometime in early October" 2024 during a "conversation with our counsel." Foy Dep. Tr. 14:4-15:17. And while Nippon Shinyaku and NS Pharma contend below that they "pre-emptively disclosed" Mr. Foy "upon learning that Mr. Gendron had departed NS Pharma, Inc.," Mr. Foy testified that Nippon Shinyaku and NS Pharma's trial counsel, Krista Venegas, and their patent damages expert, Mr. Hosfield, were present on the August 2024 videoconference between Mr. Gendron and Mr. Foy where Mr. Foy was made aware of this litigation. Foy Dep. Tr. 9:20-13:22. This happened about two months before Nippon Shinyaku and NS Pharma disclosed Mr. Foy to Sarepta. When Sarepta asked Mr. Foy about information contained in various NS Pharma market forecast documents—a topic that Nippon Shinyaku/NS Pharma said Mr. Foy has knowledge about on its November 8, 2024 Third Supplemental Initial Disclosures—Mr. Foy stated he had not seen the documents before and/or was unable to answer questions about their contents. *See, e.g.,* Foy Dep. Tr. 51:13-52:19 (had not seen NS Pharma spreadsheet with tabs titled "Forecast Model" and "Calendar Year Summary"), *id.* at 55:1-6 (not familiar with the form of this report when it was developed): *id.* at 57:20-58:15 (did not know how the reported average number of patients on therapy was generated). Indeed, Mr. Foy testified ***on redirect*** that he did not have any reason to review NS Pharma's profit and loss statements (and the information in them, another topic Nippon Shinyaku/NS Pharma said he has knowledge on) that pre-dated his September 2023 arrival at NS Pharma (Foy Dep. Tr. 177:18-179:12) and that he did not know whether information in NS Pharma's profit and loss statements were used to calculate the operating margin for NS Pharma

(Foy Dep. Tr. 179:13-180:7). Further, Nippon Shinyaku/NS Pharma used the attorney-client privilege to instruct Mr. Foy not to disclose the expected subject matter of his proposed trial testimony, preventing Sarepta from inquiring into Mr. Foy's basis for knowing whatever it is that Nippon Shinyaku/NS Pharma intend for him to testify about at trial. Foy Dep. Tr. 15:25-16:9.

The evening after Mr. Foy's deposition, Sarepta notified Nippon Shinyaku/NS Pharma that, as Mr. Foy's deposition confirmed he has no personal knowledge of relevant information, Sarepta was maintaining its objection to his testimony. But, in the interest of avoiding burdening the Court with this issue, Sarepta offered a compromise that would eliminate the need for Mr. Foy's (and others') testimony by stipulating to the admissibility without need for a sponsoring witness of certain exhibits. Nippon Shinyaku/NS Pharma rejected this compromise. Because Nippon Shinyaku/NS Pharma did not timely disclose Mr. Foy, failed to show he has personal knowledge of relevant information, and used the attorney-client privilege to block Sarepta's investigation of the same, Mr. Foy should not be permitted to testify at trial.**]**

b. **Nippon Shinyaku/NS Pharma's Position:** Despite Sarepta's complaints, Nippon Shinyaku timely disclosed Donald Foy as a witness, and Mr. Foy should be permitted to testify at hearing regarding anything within his personal knowledge—including commercial aspects of NS Pharma relevant to damages in this case.

Specifically, Nippon Shinyaku originally presented Gardner Gendron (US Vice President of Commercial at NS Pharma) as its 30(b)(6) witness on topics relating to NS Pharma, and Nippon Shinyaku identified Mr. Gendron on its May 2024 witness list to provide testimony describing the commercial operations of NS Pharma in order to provide certain information relevant to damages.

However, upon learning that Mr. Gendron had departed NS Pharma, Inc., NS Pharma pre-emptively disclosed Mr. Don Foy as the new US Vice President of Commercial on its Amended Witness List October 30, 2024 and provided an Amended Initial Disclosure indicating the scope of Mr. Foy's relevant knowledge and also confirmed that Mr. Foy's anticipated testimony included previously produced and which documents. Nippon Shinyaku and NS Pharma made Mr. Foy available for a full-day of deposition on November 20, 2024, and Sarepta deposed Mr. Foy. During his deposition, Mr. Foy demonstrated that he has a great deal of personal knowledge regarding the commercial operations of NS Pharma, including based on his time as NS Pharma's Head of Sales, which positioned him to succeed Mr. Gardner as US Vice President of Commercial at NS Pharma. Specifically, Mr. Foy testified in detail about the relationship between NS Pharma and Nippon Shinyaku. *See* Foy Dep. Tr. 24:10-26:5. He explained that he understands the process for submitting NS Pharma sales forecasts to Nippon Shinyaku because he is currently in the process of preparing the forecast for fiscal year 2025. *Id.* at 28:5-29:16. He described in detail the operations of NS Pharma's patient services group, which coordinates patient access to VILTEPSO. *Id.* at 36:23-40:21. He testified at length about NS Pharma's marketing operations with respect to VILTEPSO. *Id.* at 47:8-49:8. Mr. Foy also testified about NS Pharma's P&L statements, including the fact that he now receives and reviews P&L statements as part of his responsibilities as Vice President of Commercial. *Id.* at 83:13-105:18; *see also id.* at 84:25-85:4 ("Q. Did you gain access to this P&L statement in the course of your normal role as VP of commercial or was it for purposes of this litigation only? A. In my normal role as VP of commercial."). Mr. Foy also provided extensive testimony on the relationships that NS Pharma has with various commercial partners, including Nippon Shinyaku, US distributors, and specialty pharmacies. *See e.g., id.* at 120:19-132:22; 181:20-182:6.

Sarepta's complaint with Mr. Foy appears to be that he may not have personal knowledge of specific documents or information that predates his arrival at NS Pharma.[23] However, this is not a basis to preclude Mr. Foy from testifying at all—indeed, Nippon Shinyaku and NS Pharma do not intend to call Mr. Foy to testify about things for which he does not have personal knowledge. To the extent Sarepta believes that Mr. Foy lacks knowledge about certain topics, Sarepta should raise any objection to Mr. Foy's testimony due to a lack of foundation on a case-by-case basis, or should address his supposed lack of knowledge during examination. In short, (1) Mr. Foy was timely disclosed as soon as it became evident that he would testify following the departure of Mr. Gendron, (2) Mr. Foy was made available for deposition to allow Sarepta to inquire about Mr. Foy's knowledge regarding relevant topics, (3) Mr. Foy has personal knowledge regarding the commercial operations of NS Pharma, which are relevant to damages in this case, and (4) Sarepta can object to any specific testimony from Mr. Foy for lack of foundation and/or cross examine Mr. Foy about his knowledge of certain topics. Given these facts, there is no basis to preclude Mr. Foy from testifying at trial.**]**

94. Nippon Shinyaku and NS Pharma's motion for a finding of no injury-in-fact and no lost profits for the period of April 1, 2021 to May 11, 2022, as well as to exclude late-produced evidence by Sarepta, and Sarepta's opposition thereto can be found at D.I. 568 and D.I. 572 (under seal) and D.I. 581, D.I. 587, and D.I. 588 (public). The Court has not ruled on this motion.

[23] Sarepta also complains that "Nippon Shinyaku/NS Pharma used the attorney-client privilege to instruct Mr. Foy not to disclose the expected subject matter of his proposed trial testimony, preventing Sarepta from inquiring into Mr. Foy's basis for knowing whatever it is that Nippon Shinyaku/NS Pharma intend for him to testify about at trial." This is simply not true. Counsel for Nippon Shinyaku/NS Pharma instructed Mr. Foy not to answer one single question—"What do you expect to be the subject matter of your testimony." Foy Dep. Tr. at 15:25-16:9. This instruction was proper, as Mr. Foy's knowledge of his expected testimony was acquired purely on the basis of discussions with counsel. At no point was Sarepta prevented from inquiring into Mr. Foy's personal knowledge about any topic.

95. Nippon Shinyaku and NS Pharma's letter Motion to Strike Certain Supplemental Opinions from Sarepta's Economic Expert John Jarosz can be found at D.I. 640 and 641. Nippon Shinyaku and NS Pharma filed this motion at 4:48 pm Eastern on Friday, November 22, 2024, after the parties met and conferred on the proposed motion earlier that day at 10 am Eastern. Sarepta plans to respond to Nippon Shinyaku and NS Pharma's motion earlier than the December 2, 2024 deadline that would apply under the Scheduling Order (*see* D.I. 143 at ¶6(b)). The Court has not ruled on this motion.

C. Jury Notes

96. The parties agree that the jurors be permitted to take handwritten notes during the presentations of the parties and that jurors be permitted to bring these notebooks and handwritten notes into the deliberation room. The parties further propose that the jurors be instructed not to share the notebooks with each other (though they can discuss the contents of their notes) and that the notebooks be collected and destroyed after the verdict without review. No later than **4 p.m.** on the Friday before trial commences, the parties shall submit to the Court copies of a proposed juror notebook, which shall contain a copy of all the NS Patents and Wilton Patent, a tab for the preliminary jury instructions, a section for juror notes, a chart containing the Court's constructions of disputed claim terms, and any other materials that the parties can jointly agree should be included.

D. Handling of Confidential Information at Trial

97. The parties anticipate that the majority of the trial will be open to the public and not sealed unless a party specifically requests that a particularly sensitive portion be sealed. The parties presently anticipate making such a request for the portions of the trial regarding patent damages. If a party makes such a request, subject to the Court's approval, and for good cause shown, the courtroom shall be cleared of those individuals not qualified under the Protective Order

entered in this case, except that each party's corporate representative may remain in the courtroom throughout the entirety of trial. Where such a request is approved, the party making such a request shall be charged for the entire time necessary to rule on the request and the time it takes to clear and re-open the courtroom.

98. Insofar as the Protective Order restricts the dissemination and use of any material, such restrictions shall not apply to the introduction of evidence at trial. Insofar as the MCA between Nippon Shinyaku and Sarepta restricts the dissemination and use of any material, such restrictions shall not apply to the introduction of evidence at trial. To the extent such documents are admitted into evidence or published to the jury at trial on monitors while the trial is open to the public, this shall not constitute a violation of the Protective Order or the MCA and such documents shall no longer be subject to any restrictions under the Protective Order.

E. Federal Judicial Center Introduction to the Patent System Video

99. The parties stipulate that the video will be played as part of the Court's preliminary jury instructions, and that the time incurred in playing the video will not be charged to the parties.

F. Set-Up of Electronic and Computer Equipment

100. The parties request that the Court grant them access to the Courtroom one or two business days before trial begins (at the Court's convenience), to allow them to set up electronic and computer devices to be used during trial.

G. Dispute Resolution Procedures

101. If after meeting and conferring, the parties are unable to resolve their objections to demonstratives, witnesses, or other evidence, the objecting party shall provide its position(s) promptly after the conclusion of the meet and confer and in no event later than 11:00 p.m. The responding party shall provide its responsive position by 11:30 p.m. By 12:00 a.m. (midnight) Delaware counsel, on behalf of the parties, shall notify the Court by email

(jlh_civil@ded.uscourts.gov) of any objections to demonstratives, witnesses, or other evidence to be presented that trial day (or, in the case of deposition designations, two days before the day of anticipated use, *see supra* ¶ 52). The parties shall attach to the email a joint pleading identifying the disputes and digital copies of all relevant demonstratives, exhibits, or other evidence with the disputed passages highlighted. The parties shall state their position on each dispute in one to two sentences. By 8:15 a.m., the parties shall provide the Court with two (2) courtesy copies of the submission. The parties shall leave the courtesy copies on the lectern in the courtroom.

XVII. SETTLEMENT

102. The parties have engaged in a good faith effort to explore the resolution of the controversy by settlement, but have been unable to reach any agreement that would resolve this matter.

IT IS HEREBY ORDERED that this Final Pretrial Order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

DATED: _____

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UNITED STATES DISTRICT JUDGE